

I/We Claim:

1. A neuromuscular stimulation assembly comprising
at least one electrode sized and configured for
implantation in a targeted neural or muscular tissue
5 region,

a percutaneous lead electrically coupled to the
electrode and including an exposed region projecting
through an external skin surface,

a carrier sized and configured to be worn on the
10 external skin surface,

circuitry carried on-board the carrier configured to
generate a stimulation pulse, and

an electrode connection element carried on-board the
carrier that is electrically coupled to the circuitry,
15 the electrode connection element being sized and
configured to electrically engage at least a portion of
the exposed region of the lead to electrically couple the
electrode to the circuitry to percutaneously apply the
stimulation pulse to the tissue region.

20 2. An assembly according to claim 1

further including a power input bay carried on-board
the carrier that is electrically coupled to the
circuitry, the power input bay being sized and configured
to hold a power source.

25 3. An assembly according to claim 1

further including a power input bay carried on-board
the carrier that is electrically coupled to the
circuitry, the power input bay being sized and configured
to hold a power source that can be released and replaced.

30 4. An assembly according to claim 3

further including instructions prescribing the
release and replacement of the power source according to
a preset schedule.

5. An assembly according to claim 2 or 3

35 wherein the power source comprises a battery.

6. An assembly according to claim 1
further including a communication bay carried on-
board the carrier that is electrically coupled to the
circuitry, the communication bay being sized and
5 configured to establish a communication link between the
circuitry and an external device.

7. An assembly according to claim 6
wherein the communication bay is also sized and
configured to hold a power source.

10 8. An assembly according to claim 6
wherein the communication bay is also sized and
configured to hold a power source that can be released
and replaced.

9. An assembly according to claim 8
15 further including instructions prescribing the
release and replacement of the power source according to
a preset schedule.

10. An assembly according to claim 7 or 8
wherein the power source comprises a battery.

20 11. An assembly according to claim 1
wherein the circuitry includes programmable code
that governs generation of the stimulation pulse.

12. An assembly according to claim 11
further including a communication bay carried on-
25 board the carrier that is electrically coupled to the
circuitry, the communication bay being sized and
configured to establish a communication link between the
circuitry and an external device to program the
programmable code.

30 13. An assembly according to claim 12
wherein the communication bay is also sized and
configured to hold a power source.

14. An assembly according to claim 13
wherein the communication bay is also sized and
35 configured to hold a power source that can be released

and replaced.

15. An assembly according to claim 14
further including instructions prescribing the
release and replacement of the power source according to
5 a preset schedule.

16. An assembly according to claim 13 or 14
wherein the power source comprises a battery.

17. An assembly according to claim 1
further including an electronics bay carried on-
10 board the carrier that is sized and configured to hold
the circuitry.

18. An assembly according to claim 1
further including an electronics bay carried on-
board the carrier that is sized and configured to hold
15 the circuitry for selective release from the carrier.

19. An assembly according to claim 1
further including a region carried on-board the
carrier sized and configured to adhere the carrier to the
external skin surface and to accommodate selective
20 detachment of the carrier from the external skin surface.

20. An assembly according to claim 1
wherein the carrier comprises separable sections
that can be manipulated to open the carrier to
accommodate passage of the exposed region of the lead
25 into electrical engagement with the electrode connection
element and to close the carrier to capture the exposed
region of the lead within the electrode connection
element.

21. An assembly according to claim 1 or 20
30 wherein the electrode connection element comprises a
trough to route the exposed region of the lead.

22. A neuromuscular stimulation system comprising
a carrier sized and configured to be worn on an
external skin surface at or near a targeted neural or
35 muscular region, the carrier including circuitry

configured to generate a stimulation pulse, a power input bay sized and configured to hold a battery for the circuitry that can be released and replaced for recharging the circuitry, and an electrode connection element that is sized and configured to electrically engage an electrode lead for an electrode that has been percutaneously implanted in the targeted tissue region, to percutaneously apply the stimulation pulse to the targeted tissue region,

instructions prescribing the release and replacement of the battery according to a preset schedule, and a supply of batteries for recharging the circuitry according to the preset schedule.

23. A system according to claim 22 wherein the circuitry includes programmable code governing generation of the stimulation pulse.

24. A system according to claim 23 wherein the carrier includes means for establishing a communication link between the circuitry and an external device to program the programmable code.

25. A method for providing a neuromuscular stimulation function using an assembly as defined in claim 1 or a system as defined in claim 22.

26. A method according to claim 25 wherein the neuromuscular stimulation function includes a function selected from a group comprising (i) maintenance of muscle function; (ii) tissue or bone regeneration; (iii) continuous active motion therapy; (iv) anti-scarring treatment; (v) diagnostic assessment; (vi) neuroplasticity therapy; (vii) anti-spasm therapy; (viii) pain therapy; (ix) post-surgical reconditioning; (x) anti-thrombosis therapy; and (xi) treatment of osteoporosis.

27. A percutaneous electrode assembly comprising a flexible body including an electrically conductive

region, a tissue penetrating region for implantation of the electrically conductive region in a targeted tissue region, and a percutaneous lead electrically coupled to the electrically conductive region,

5 an anchoring element on the flexible body to resist movement of the electrically conductive region within tissue, and

 an introducer having an interior lumen sized and configured to receive the flexible body and shield the
10 anchoring element from contact with tissue while the electrically conductive region is placed to a desired position within tissue, the introducer also being sized and configured to accommodate advancement of the
15 anchoring element beyond the interior lumen for contact with tissue to resist movement of the electrically conductive region placed in the desired position.

28. A method of implanting a percutaneous electrode comprising the steps of

 providing a percutaneous electrode with an anchoring
20 element to resist movement of the percutaneous electrode within tissue,

 inserting the percutaneous electrode within an introducer that shields the anchoring element from contact with tissue,

25 implanting the percutaneous electrode while inserted within the introducer, to place the percutaneous electrode in a desired location within tissue, and

 withdrawing the introducer to place the anchoring element in contact with tissue, thereby resisting
30 movement of the percutaneous electrode from the desired position.

29. A method according to claim 28

 further including, during the implanting step, a step of coupling the percutaneous electrode to a
35 stimulating circuit to provoke a tissue stimulation

Atty. Docket No.: 9469.18533

- 30 -

response to place the percutaneous electrode in the desired location.